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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,228	02/21/2002	Shuji Hinuma	46342/57113	1875
21874	7590	08/12/2005	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			LOCKARD, JON MCCLELLAND	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 08/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/069,228	Applicant(s) HINUMA ET AL.	
	Examiner Jon M. Lockard	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2005.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-11 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1 and 3-11 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☒ The drawing(s) filed on 27 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Amendment filed 27 April 2005 has been received and entered in full. Claims 1 and 3 have been amended, claim 2 has been cancelled, and claims 4-11 have been added. Therefore, claims 1 and 3-11 are pending and are the subject of this Office Action.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections and/or Rejections

Priority

3. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. PCT/JP00/05639, filed on 23 August 2000. 4. Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action.

Drawings

5. The objection to the drawings as set forth at page 3 (§7) of the previous Office Action (mailed 27 January 2005) is withdrawn in view of Applicant's amendment of drawing wherein the label "Fig. 1" has been deleted (filed 27 April 2005).

Specification

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6. The objections to the Specification as set forth as page 4 (¶9-11) of the previous Office Action (mailed 27 January 2005) is withdrawn in view of Applicant's amendments (filed 27 April 2005).

Claim Rejections

7. The rejection of claims 1 and 3 under 35 U.S.C. §112 ¶2 as set forth at page 5 (¶14) in the previous Office Action (mailed 27 January 2005) is withdrawn in view of Applicant's amendment of claims 1 and 3 which now recite "expressing" (filed 27 April 2005).

8. The rejection of claims 1 and 3 under 35 U.S.C. §112 ¶2 as set forth at page 5 (¶16) in the previous Office Action (mailed 27 January 2005) is withdrawn in part in view of Applicant's amendment of claims 1 and 3 (filed 27 April 2005).

9. The rejection of claims 1 and 3 under 35 U.S.C. §112 ¶2 as set forth at page 5 (¶17) in the previous Office Action (mailed 27 January 2005) is withdrawn in view of Applicant's amendment of claims 1 and 3 which now recite method steps (filed 27 April 2005).

10. The rejection of claims 1 and 3 under 35 U.S.C. §112 ¶2 as set forth at pages 5-6 (¶18) in the previous Office Action (mailed 27 January 2005) is withdrawn in view of Applicant's amendment of claims 1 and 3 which deleted the term "to be measured" (filed 27 April 2005).

11. The rejection of claim 1 under 35 U.S.C. §112 ¶2 as set forth at page 6 (¶19) in the previous Office Action (mailed 27 January 2005) is withdrawn in view of Applicant's amendment of said claim (filed 27 April 2005).

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12. The rejection of claim 1 under 35 U.S.C. §112 ¶2 as set forth at page 6 (¶20) in the previous Office Action (mailed 27 January 2005) is withdrawn in view of Applicant's amendment of said claim which now relates back to the preamble (filed 27 April 2005).

13. The rejection of claims 1 and 3 under 35 U.S.C. 102(b) as being anticipated by Aiyar et al. as set forth as pages 6-7 (¶22) in the previous Office Action (mailed 27 January 2005) is withdrawn in view of Applicant's amendment of said claims (filed 27 April 2005).

14. The rejection of claims 1 and 3 under 35 U.S.C. 102(b) as being anticipated by Zhou et al. as set forth as page 7 (¶23) in the previous Office Action (mailed 27 January 2005) is withdrawn in view of Applicant's amendment of said claims (filed 27 April 2005).

Maintained and/or New Rejections

Claim Rejections - 35 USC § 112, 2nd Paragraph

15. Claims 1 and 3-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

16. Claim 1 and 3 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for reasons set forth at page 5 (¶15) in the previous Office Action (mailed 27 January 2005). As stated at page 5 of the previous Office Action, since it is unclear how much the structure of the candidate compound can deviate from a referenced structure and still have "a common structure", the metes and bounds of the claim cannot be determined.

17. At pages 12-13 of the response (filed 27 April 2005), Applicants refer the Examiner to the discussion of such as pages 34-35 of the Specification. Applicants argue that those skilled in

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the art would be able to recognize an appropriate extent of deviation from a common structure from a referenced structure based on the description at pages 34-35 and related descriptions in the present specification.

18. Applicant's arguments have been fully considered but they are not persuasive for the following reasons. The discussion of "common structures" at pages 34-35 is noted but vague, fails to breathe life and meaning into the term, is exemplary rather than limiting, and thus is insufficient to render the claims definite. Furthermore, it is inappropriate to read limitations in the specification, much less the general knowledge of one of ordinary skill in the art, into the claims. The claims must independently define the invention for which patent protection is sought. It is noted that the discussion of "R-X-NH₃ structure at C-terminus" as an example of a common structure refers to when a specific receptor, namely FM-3, is the orphan receptor protein, and the instant claims are not limited in scope to the FM-3 receptor.

19. Claims 1 and 3 are further rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Part (ii) of each claim, "extracting a common structure", does not set forth any steps involved in the method/process, therefore it is unclear what method/process is encompassed by the claims.

20. Claim 1 recites the limitation "test compound (b)" in part (iii) line 5 of the claim. There is insufficient antecedent basis for this limitation in the claim.

21. Claims 1 and 3 are rejected as being indefinite because it is unclear what is being compared. For example, claim 1 recites three different groups of compounds (test compound A, ligand candidate compounds, and test compound B), and it is unclear what compounds are

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encompassed by the limitation “if there is an increase in the amount of specific binding as compared to non-specific binding”, as recited in part (iii) lines 9-10 of the claim. Likewise, since claim 3 recites two different groups of compounds (test compound A and ligand candidate compounds), it is unclear what is encompassed by the limitation “which shows an increase in the amount of specific binding to said orphan receptor as compared to non-specific binding”, as recited in part (iv) of the claim.

22. Claims 4 and 8 are rejected as being indefinite for reciting the phrase “a common three-dimensional structure”. Since neither the art nor the specification provides an unambiguous definition of the phrase “a common three-dimensional structure”, the claims are indefinite.

23. Claims 5-6 and 9-10 are rejected as being indefinite because it is unclear if the terms “protein” and “peptide” are intended to refer to the same or different compounds.

Claim Rejections - 35 USC § 112, 1st Paragraph (New Matter)

24. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

25. Claims 1 and 3-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.** Claims 1 and 3 recite “*extracting* a common

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structure”, claims 4 and 8 recite a “common *three-dimensional* structure”, and claims 7 and 11 recite a “branched” compound. After extensive review, the Examiner is unable to find, in the Specification as originally filed, support for these newly added limitations in the claims. These newly added limitations are not expressly asserted, nor do they flow naturally from the Specification as originally filed.

Summary

26. No claim is allowed.

27. Since the newly introduced step (part (ii) of claims 1 and 3) is indefinite, a meaningful search of the scientific literature cannot be performed. As evidenced by the art made of record below, methods of identifying ligands via measuring binding, competitive binding, or activity are well-known in the art. Therefore, if there is a patentable aspect of the instant application, the patentability of the claimed methods appears to rest on the particular receptor that is being utilized. Applicants are encouraged to draft claims accordingly should they request to continue examination.

28. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- 1.) U.S. Pat. No. 6,586,191 B2 teaches methods of screening compounds which bind to a human galanin receptor using binding and competitive binding assays.
- 2.) U.S. Pat. No. 6,368,812 B1 teaches methods of screening compounds which bind to or activate a human galanin receptor via a second messenger functional assay.

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29. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback**, can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

JML

August 8, 2005

A handwritten signature in dark ink, reading "Lorraine Spector". The signature is fluid and cursive, with a large, stylized initial "L".

**LORRAINE SPECTOR
PRIMARY EXAMINER**